## Remarks

Upon entry of these amendments, claims 12, 14-16 and new claims 28-38 will be pending. Claims 1-11 and 13 have been canceled without prejudice. No new matter has been added. The phrase "functional derivative" is supported at least in the specification at pages 13, first paragraph. Methods for identifying an agent that modulates B cell development, and new claims 34-35 are supported in the specification at page 4, second paragraph; page 28, first paragraph; and in Figure 1. New claims 36-38 are supported in the claims as originally filed, and in the specification at page 3. Applicant respectfully request reconsideration and allowance of the amended claims in view of the remarks below.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-11 and 13 have been canceled, rendering the rejections moot as to these claims. The pending claims have been amended to delete allegedly indefinite terms and for clarity.

The invention as claimed provides methods for screening agents that inhibit T lymphocyte differentiation and/or modulate B cell development, based on the discovery that IP3KB is an important component in T cell and B cell development. In particular, the amended claims recite the active steps of (a) screening agents that inhibit the cellular activity of IP3KB; and b) testing the agents for ability to inhibit T lymphocyte development or function and/or modulate B cell development. Accordingly, the claims are clear and definite, and Applicant respectfully requests that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-6 and 8-16 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully disagree, and address the rejection in view of the amended claims.

The specification provides more than adequate support for the amended claims. For example, the specification teaches that functional derivatives of IP3K may be used in the methods of the invention. (See e.g., specification at pages 11-13). The specification also

describes amino acid sequences encoding IP3KB, and as the Office recognizes, defines "substantially identical" to be sequences at least 90 % identical. However, the Office relies on *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398, to support its rejection.

"Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed." *Enzo Biochem*, 296 F.3d 1316, 1324 (Fed. Cir. 2002). In *Eli Lilly*, the patent at issue contained no sequence information for human cDNA to support a claim specific to a microorganism containing human insulin cDNA. Unlike *Eli Lilly*, the specification in the present application describes amino acid sequences encoding IP3KB, and also describes programs known in the art for determining percentage of sequence identity. Thus, the claims have more than adequate written description and Applicant respectfully requests that this rejection be withdrawn.

Claims 1-6 and 8-16 were also rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. As amended, the claims recite the active steps of (a) screening agents that inhibit the cellular activity of IP3KB; and b) testing the agents for ability to inhibit T lymphocyte development or function and/or modulate B cell development. As the Office acknowledged, the specification demonstrates that IP3KB deficient mice have impaired T cell development. Furthermore, mutant mice lacking IP3KB were found to have an altered splenic B cell maturation. Thus, the amended claims are enabled, and Applicant respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1, 3-4, 6 and 8-11 are rejected under 35 U.S.C. § 102(a), as allegedly being anticipated by Chang *et al.*, *ChemBiochem.* 3:897-901 (2002). These claims have been canceled without prejudice, rendering this rejection moot.

Claims 1-4, 6 and 8-15 are rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by da Silva *et al.*, *J. Biol. Chem.* 269:12521-12526 (1994). The Office alleges that "since one activity of IP3KB is converting IP3 to IP4 ..., da Silva et al. have assayed for a cellular activity of IP3KB (including accession No. NP_002212)." (Office Action, page 8). Applicant respectfully disagrees.

Anticipation requires that the prior art teach each and every element of the invention. The da Silva reference is silent regarding IP3KB, let alone IP3KB having specified amino acid sequences and a method comprising assaying a cellular activity of IP3KB. Furthermore, as discussed in the Declaration of Michael P. Cooke under 37 C.F.R. § 1.132, attached at Exhibit 1, adriamycin does not inhibit IP3KB.

Because da Silva reference does not teach IP3KB or an agent that inhibits IP3KB, da Silva does not anticipate. Thus, Applicant respectfully requests that this rejection be withdrawn.

New claims 28-38

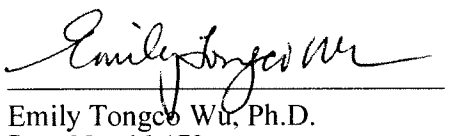
New claims 28-38 depend upon claim 12, and contain all the limitations of claim 12. Accordingly, claims 28-38 are novel. Furthermore, claims 36-38 relate to diseases with a known T cell or B cell linkage, and are enabled. (See e.g., Browning J., "B cells move to centre stage: novel opportunities for autoimmune disease treatment," Nature Reviews 5:564-576 (2006), attached at Exhibit 2; Dalakas, M., "B cells in the pathophysiology of autoimmune neurological disorders: A credible therapeutic target," Pharmacology & Therapeutics 112:57-70 (2006), attached at Exhibit 3; and Prinz, JC, "The role of T cells in psoriasis," European Academy of Dermatology and Venereology 17:257-270 (2003), attached at Exhibit 4).

Conclusion

In summary, the claims have been amended to obviate the rejections, and Applicant requests that claims 12, 14-16 and new claims 28-38 be passed to issue. If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at (858) 812-1539. **Prior to issuance of a final Office Action, the undersigned respectfully requests a telephonic interview with the Examiner.**

If the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-1885** referencing docket No. P1097US10.

Respectfully submitted,



Emily Tongco Wu, Ph.D.
Reg. No. 46,473

**Customer No.: 29490**
Tel: (858) 812-1539
Fax: (858) 812-1909